Drug Utilization Review Board Meeting Minutes, Open Session October 11, 2017		
Drug Utilization Review Board Meeting Location: DXC Technology, Building #283, Capital Room 6511 SE Forbes Ave, Topeka, KS 66619	**DUR Board Members Present** Moneeshindra Mittal, MD, Chair LaTonyua Rice, Pharm.D., CGP Judy Dowd, PA-C Tim Heston, DO Roger Unruh, DO **DUR Board Members Absent** James Backes, Pharm.D. John Kollhoff, Pharm.D., Interim Chair **DHCF Staff Present** Annette Grant, RPh Carol Arace, Sr. Administrative Assistant **DXC Technology Staff Present** Karen Kluczykowski, RPh Ellen McCaffrey, BSN, MSN Karen Kluczykowski, RPh **HID Staff Present** Taylor DeRuiter, Pharm.D. Ariane Casey, Pharm.D. (Phone) **MCO Staff Present** Angie Zhou, Pharm.D., Sunflower Health Plan Jennifer Murff, RPh: United Healthcare Community Plan Lisa Todd, RPh: Amerigroup	**Representatives:** Blake Baretsky, Genentech; Melissa Basil, Abbvie; Jim Baumann, Pfizer; Jeanie Brown, Novartis; Edie Dodson, Sandti; Jeff Eskin, Celgene; Brent Fushimi, Arbor; Deran Grota, Teva; Brant Hildebrand, Gilead; Laura Hill, Abbvie; Heather Jones, Novartis; Meghan Kerrigan, Merck; Phil King, Pfizer; Berend Koops, Merck; Yvonne Luu, Teva; Scott Maurice, B.I.; Terry McCurren, Otsuka; Julie McDavitt, B.I.; Roberta Nevwirth, GSR; Dean Patice, PCYC; Bryce Platt, Pfizer; Michelle Puyear, Gilead; Chris Stanfield, Sipomis; Amanda Weber, Celgene

TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Mittal called the meeting to order at 10:09am.	
A. Announcements	Ms. Grant provided the standard parking announcement.	
II. Old Business **A. Review and Approval of July 26, 2017 Meeting Minutes**	**Board Discussion:** None.	Dr. Unruh moved to accept the minutes as written. Dr. Heston seconded the motion. The July 26, 2017 minutes were approved as written unanimously.
III. New Business **A. PDL Committee New Business** 1. PDL Pre-Approval	**Background:** At the September 2017 PDL meeting, the committee approved the pre-approval for drug molecule dose, dose form, device, IR/ER of CURRENT PDL drug.	Ms. Dowd moved to approve. Dr. Unruh seconded the motion.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
i. Explanation	**Public Comment:** None. **Board Discussion:** Ms. Grant requested the DUR Board approve what the PDL has already approved.	The DUR Board approved the PDL Committee's Pre-Approval unanimously.
B. New Preferred Drug List (PDL) Class 1. Hepatitis C Refractory Treatment Agents i. Approve/Reject of the creation of this class	**Background:** At the September 2017 PDL meeting, the committee approved the addition of the Hepatitis C Refractory Treatment Agents to the PDL. Dr. DeRuiter noted to the Board that 'Non-Preferred PDL PA Criteria' is not accurate for this. The Board is to only to approve/reject of the creation of this class. **Public Comment:** None. **Board Discussion:** Dr. Mittal questioned if all six agenda items could be voted on as one. Ms. Grant noted they had to be voted on separately.	Dr. Unruh moved to approve. Dr. Rice seconded the motion. The new Hepatitis C Refractory Treatment Agents Class was approved unanimously.
B. New Preferred Drug List (PDL) Class 2. Topical Corticosteroids – Mild Potency i. Approve/Reject of the creation of this class	**Background:** At the September 2017 PDL meeting, the committee approved the addition of the Topical Corticosteroids – ~~Mid~~ Mild Potency to the PDL. **Public Comment:** None. **Board Discussion:** Ms. Grant provided resource information from the potency chart provided by the National Psoriasis Foundation to the Board on how these classes were determined. Per Ms. Grant the correct wording is 'Mild Potency'.	Ms. Dowd moved to approve. Dr. Unruh seconded the motion. The new Topical Corticosteroids – Mild Potency Class was approved unanimously.
B. New Preferred Drug List (PDL) Class 3. Topical Corticosteroids – Intermediate Potency i. Approve/Reject of the creation of this class	**Background:** At the September 2017 PDL meeting, the committee approved the addition of the Topical Corticosteroids – Intermediate Potency to the PDL. **Public Comment:** None. **Board Discussion:** None.	Dr. Heston moved to approve. Dr. Unruh seconded the motion. The new Topical Corticosteroids – Intermediate Potency Class was approved unanimously.
B. New Preferred Drug List (PDL) Class 4. Topical Corticosteroids – High Potency i. Approve/Reject of the creation of this class	**Background:** At the September 2017 PDL meeting, the committee approved the addition of the Topical Corticosteroids – High Potency to the PDL. **Public Comment:** None. **Board Discussion:** None.	Dr. Unruh moved to approve. Ms. Dowd seconded the motion. The new Topical Corticosteroids – High Potency Class was approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
B. New Preferred Drug List (PDL) Class 5. Topical Fluorouracil Agents i. Approve/Reject of the creation of this class	**Background:** At the September 2017 PDL meeting, the committee approved the addition of the Topical Fluorouracil Agents to the PDL. **Public Comment:** None. **Board Discussion:** None.	Ms. Dowd moved to approve. Dr. Rice seconded the motion. The new Topical Fluorouracil Agents Class was approved unanimously.
B. New Preferred Drug List (PDL) Class 6. Topical Rosacea Agents i. Approve/Reject of the creation of this class	**Background:** At the September 2017 PDL meeting, the committee approved the addition of the Topical Rosacea Agents to the PDL. **Public Comment:** None. **Board Discussion:** The Board questioned the preferred/non-preferred step. Ms. Grant noted, once an agent is considered clinically equivalent by the PDL committee, the decision of preferred/non-preferred status is determined by the State.	Dr. Unruh moved to approve. Dr. Heston seconded the motion. The new Topical Rosacea Agents Class was approved unanimously.
C. Revised Prior Authorization (PA)Criteria 1. Daraprim® (pyrimethamine) i. Revised PA Criteria	**Background:** Daraprim had a typographical error during the initial approval in July 2017. **Public Comment:** None. **Board Discussion:** Tabled until the next DUR meeting to allow the State to clarify additional issues.	Table to next DUR meeting.
C. Revised Prior Authorization (PA)Criteria 2. Humira® (Cyltezo® [adalimumab-adbm]) i. Revised PA Criteria	**Background:** Cyltezo is the second biosimilar available for Humira. Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Prior authorization criteria for this agent were last revised in April 2017. Since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Cyltezo.	Dr. Heston moved to approve. Ms. Dowd seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	PA Criteria Policy/Clarification Number: E2003-053 Initial Approval: November 9, 2005 Revised Dates: October 11, 2017; April 12, 2017; October 12, 2016 April 13, 2016; January 13, 2016; January 14, 2015 April 10, 2013; June 15, 2011; January 12, 2011 November 12, 2008; July 9, 2008; March 12, 2008 **CRITERIA FOR PRIOR AUTHORIZATION** Humira® (adalimumab), Amjevita® (adalimumab-atto), Cyltezo® (adalimumab-adbm) **PROVIDER GROUP** Pharmacy **MANUAL GUIDELINES** The following drug requires prior authorization: Adalimumab (Humira®, Amjevita®, Cyltezo®) **CRITERIA FOR RHEUMATOID ARTHRITIS (RA):** (must meet all of the following) • Patient must have a diagnosis of rheumatoid arthritis • Must be prescribed by a rheumatologist • Evaluation for latent tuberculosis (TB) with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • Patient must be on concomitant methotrexate with dosing of adalimumab 40 mg every other week. For patients contraindicated or not able to take concomitant methotrexate, dosing frequency may be increased to adalimumab 40 mg every week. **CRITERIA FOR JUVENILE IDIOPATHIC ARTHRITIS (JIA):** (must meet all of the following) • Patient must have a diagnosis of juvenile idiopathic arthritis • Must be prescribed by a rheumatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 2 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days **CRITERIA FOR PSORIATIC ARTHRITIS (PSA):** (must meet all of the following) • Patient must have a diagnosis of psoriatic arthritis • Must be prescribed by a rheumatologist or dermatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days **CRITERIA FOR ANKYLOSING SPONDYLITIS (AS):** (must meet all of the following) • Patient must have a diagnosis of ankylosing spondylitis • Must be prescribed by a rheumatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days **CRITERIA FOR CROHN'S DISEASE (CD):** (must meet all of the following) • Patient must have a diagnosis of Crohn's disease • Must be prescribed by a gastroenterologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	PA Criteria Policy/Clarification Number: E2003-053 • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient has used a conventional Crohn's disease therapy (see attached table) **OR** there is documentation of inadequate response, contraindication, allergy, or intolerable side effects to a conventional Crohn's disease therapy (see attached table) **CRITERIA FOR PEDIATRIC CROHN'S DISEASE (CD) (HUMIRA ONLY):** (must meet all of the following) • Patient must have a diagnosis of Crohn's disease • Must be prescribed by a gastroenterologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 6 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient has had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate **CRITERIA FOR ULCERATIVE COLITIS (UC):** (must meet all of the following) • Patient must have a diagnosis of ulcerative colitis • Must be prescribed by a gastroenterologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient has used a conventional ulcerative colitis therapy (see attached table) **OR** there is documentation of inadequate response, contraindication, allergy, or intolerable side effects to a conventional ulcerative colitis therapy (see attached table) **CRITERIA FOR PLAQUE PSORIASIS (PS):** (must meet all of the following) • Patient must have a diagnosis of plaque psoriasis • Must be prescribed by a rheumatologist or dermatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient has taken an oral agent for the treatment of plaque psoriasis (see attached table) **OR** patient is a candidate for systemic therapy or phototherapy **CRITERIA FOR HIDRADENTITIS SUPPURATIVA (HS) (HUMIRA ONLY):** (must meet all of the following) • Patient must have a diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II or III or Acne Inversa Severity Index [AISI] score of ≥ 10) • Must be prescribed by a rheumatologist or dermatologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days **CRITERIA FOR UVEITIS (HUMIRA ONLY):** (must meet all of the following) • Patient must have a diagnosis of non-infectious intermediate uveitis, posterior uveitis, or panuveitis • Must be prescribed by an ophthalmologist • Evaluation for latent TB with TB skin test prior to initial prior authorization approval • Patient must be 18 years of age or older • Patient has not taken another biologic agent (see attached table) in the past 30 days **LENGTH OF APPROVAL** 12 months **Public Comment:** None. **Board Discussion:** None.	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
C. Revised Prior Authorization (PA) Criteria 3. Kisqali® (ribociclib) i. Revised PA Criteria	**Background:** Kisqali is a kinase inhibitor. Prior authorization criteria were initially approved in July 2017. Since that time, a new packaging has been approved to include Kisqali in combination with Femora. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. The prior authorization criteria is being revised to include the new agent, Kisqali Femora Pack.	Dr. Heston moved to approve. Dr. Unruh seconded the motion. The criteria were approved unanimously.

PA Criteria

Initial Approval: July 26, 2017
Revised Dates: October 11, 2017

CRITERIA FOR PRIOR AUTHORIZATION

Kisqali® (ribociclib)

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Ribociclib (Kisqali®)
Ribociclib/letrozole (Kisqali Femara Co-Pack)

CRITERIA FOR APPROVAL (must meet all of the following):

- Patient must have a diagnosis of advanced or metastatic breast cancer
- The tumor must be hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative
- Medication must be used in combination with an aromatase inhibitor as initial endocrine-based therapy
- Must be prescribed by or in consultation with an oncologist
- Patient must be 18 years of age or older
- Patient must be postmenopausal
- Patient must not be pregnant or breastfeeding and be advised to not become pregnant for at least 3 weeks after the last dose
- Patient must not be on a strong CYP3A4 inducer
- Patient must have a baseline QTcF value less than 450 msec

LENGTH OF APPROVAL: 12 months

Notes:

- Recommended dosing is 600 mg once daily for 21 days followed by 7 days off treatment to comprise a complete cycle of 28 days
- When co-administered with letrozole, recommended dose of letrozole is 2.5 mg once daily continuously throughout the 28-day cycle.
- Aromatase inhibitors: Femara (letrozole), Arimidex (anastrozole), Aromasin (exemestane). Clinical trials only evaluated use with letrozole.

Public Comment:
None.
Board Discussion:
None.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
C. Revised Prior Authorization (PA) Criteria 4. Monoamine Depletors (Austedo® [deutetrabenazine], Ingrezza® [valbenazine]) i. Revised PA Criteria	**<u>Background:</u>** Prior authorization criteria were initially approved in March 2009. Since that time, two new agents have been approved. The prior authorization criteria [for Monoamine Depletors] are being revised to ensure appropriate use based upon the FDA- approved labeling information and be consistent with similar agents. The prior authorization criteria is being revised to include the new agents [(Austedo® [deutetrabenazine], Ingrezza® [valbenazine])] and corresponding indications.	Ms. Dowd moved to approve. Dr. Heston seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION

Initial Approval: March 11, 2009
Revised Dates: October 11, 217

CRITERIA FOR PRIOR AUTHORIZATION

Monoamine Depletor (VMAT2 Inhibitors)

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Deutetrabenzine (Austedo™)
Tetrabenazine (Xenazine®)
Valbenazine (Ingrezza®)

CRITERIA FOR INITIAL APPROVAL FOR TETRABENAZINE: (must meet all of the following)

- For doses ≤ 50 mg per day:
  - Diagnosis of chorea associated with Huntington's disease
  - Patient must be 18 years of age or older
  - Prescribed by or in consultation with a neurologist
  - Must NOT have any of the following:
    - Hepatic impairment
    - Be taking a monoamine oxidase inhibitor (MAOI), reserpine (at least 20 days should elapse after stopping reserpine before starting tetrabenazine), or another VMAT2 inhibitor
    - Suicidal, or untreated/inadequately treated depression
- For doses > 50 mg per day:
  - Must meet all of the above stated criteria for less than 50mg per day
  - Patient must be genotyped for CYP2D6 and must be extensive or intermediate metabolizer

CRITERIA FOR INITIAL APPROVAL FOR DEUTETRABENAZINE: (must meet all of the following)

- Must meet one of the following:
  - Diagnosis of chorea associated with Huntington's disease
  - Diagnosis of tardive dyskinesia
- Patient must be 18 years of age or older
- Prescribed by or in consultation with a neurologist or psychiatrist
- Must NOT have any of the following:
  - Hepatic impairment
  - Be taking a monoamine oxidase inhibitor (MAOI), reserpine (at least 20 days should elapse after stopping reserpine before starting deutetrabenazine), or another VMAT2 inhibitor
  - Suicidal, or untreated/inadequately treated depression
- Dose must not exceed 48 mg per day

CRITERIA FOR INITIAL APPROVAL FOR VALBENAZINE: (must meet all of the following)

- Diagnosis of tardive dyskinesia
- Patient must be 18 years of age or older
- Prescribed by or in consultation with a psychiatrist
- Must NOT have any of the following:
  - Hepatic impairment
  - Be taking a monoamine oxidase inhibitor (MAOI), reserpine (at least 20 days should elapse after stopping reserpine before starting valbenazine), or another VMAT2 inhibitor
  - Suicidal, or untreated/inadequately treated depression
- Dose must not exceed 80 mg per day

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	LENGTH OF APPROVAL: 6 months CRITERIA FOR RENEWAL (must meet all of the following): • Must meet one of the following: o Diagnosis of chorea associated with Huntington's disease and have a reduction in Total Chorea Score of at least 5 points from baseline o Diagnosis of tardive dyskinesia and have a reduction in AIMS or DISCUS score of at least 3 points from baseline LENGTH OF APPROVAL: 12 months **Public Comment:** None. **Board Discussion:** None.	
C. Revised Prior Authorization (PA) Criteria 5. Opioid Induced Constipation Agents i. Revised PA Criteria	**Background:** The agents within the Opioid Induced Constipation Agents PA Criteria have had an update to the wording for the indication. Prior authorization criteria for this agent were last revised in July 2017. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Ms. Dowd moved to approve. Dr. Heston seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Initial Approval: September 10, 2008 Revised Date: October 11, 2017; July 26, 2017; January 14, 2015 **CRITERIA FOR PRIOR AUTHORIZATION** Opioid Induced Constipation Agents **PROVIDER GROUP:** Pharmacy **MANUAL GUIDELINES:** The following drug requires prior authorization: Relistor® (methylnaltrexone) Movantik® (naloxegol) Symproic® (naldemedine) **CRITERIA for Patients with Chronic Non-Cancer Pain (All Agents):** (must meet all of the following) • Patient must be 18 years of age or older • Patient must have opioid-induced constipation • Patient must have chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation • Patient must have been on chronic opioid therapy for at least 4 weeks • Patient does not have: o Known or suspected mechanical gastrointestinal obstruction o Severe hepatic impairment (Child-Pugh Class C) (Symproic only) • Dose must not exceed: o 12mg/day for Relistor injection o 450 mg/day for Relistor tablets o 25mg/day for Movantik tablets o 0.2 mg/d for Symproic tablets **CRITERIA for Patients Receiving Palliative Care (RELISTOR INJECTION ONLY):** (must meet all of the following) • Patient must be 18 years of age or older • Patient must have opioid-induced constipation with advanced illness and be receiving palliative care • Documentation of current opioid therapy • Patient's response to standard laxative therapy has not been sufficient • Patient does not have known or suspected mechanical gastrointestinal obstruction • Dose must not exceed 12mg/day **LENGTH OF APPROVAL:** 6 months **Public Comment:** None. **Board Discussion:** Dr. Casey provided clarification concerning the FDA requiring the package inserts for all three agents to include patients who don't have current cancer but have had previous cancer. This is not approved for patients with active/current cancer.	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
C. Revised Prior Authorization (PA) Criteria 6. Adlyxin® (lixisenatide) i. Revised PA Criteria	**Background:** Adlyxin is a glucagon-like peptide 1 (GLP-1) receptor agonist. It is being proposed for a change to step therapy. Prior authorization criteria for this agent were initially approved in October 2016. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. Initial Approval: October 12, 2016 Revised Dates: October 11, 2017 **CRITERIA FOR PRIOR AUTHORIZATION** Incretin mimetic agents **PROVIDER GROUP:** Pharmacy **MANUAL GUIDELINES:** The following drug(s) require prior authorization: Lixisenatide (Adlyxin®) **CRITERIA FOR INITIAL APPROVAL FOR LIXISENATIDE:** (must meet all of the following) • Patient must be at least 18 years old. • Patient must have a diagnosis of Type 2 Diabetes. o Diagnosis of Type 2 Diabetes must be documented by HbA1c > 6.5% • Patient must have HbA1c between 6.5% - 9.0% • Patient must have a trial of a preferred metformin ER agent at a maximum tolerated dose **CRITERIA FOR RENEWAL FOR LIXISENATIDE:** (must meet one of the following) • Documented improvement of HbA1c from pretreatment levels • Achievement or maintenance of therapeutic goals (HbA1c ≤ 6.5%) **LENGTH OF APPROVAL:** 6 months **Public Comment:** None. **Board Discussion:** Ms. Grant noted the patient must try the ER version of Metformin first as part of the step therapy requirement.	Dr. Unruh moved to approve. Dr. Rice seconded the motion. The criteria were approved unanimously.
C. Revised Prior Authorization (PA) Criteria 7. Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitor Combinations i. Revised PA Criteria	**Background:** SGLT2 inhibitor combinations is being proposed for a change to step therapy. Prior authorization criteria for this agent were initially approved in October 2016. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Ms. Dowd moved to approve Dr. Heston seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Initial Approval: April 8, 2015 Revised Date: October 11, 2017; October 12, 2016 July 13, 2016 **CRITERIA FOR PRIOR AUTHORIZATION** Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitor Combinations **PROVIDER GROUP** Pharmacy **MANUAL GUIDELINES** The following drug requires prior authorization: Canagliflozin/metformin (Invokamet®, Invokamet XR®) Dapagliflozin/metformin (Xigduo XR®) Empagliflozin/linagliptin (Glyxambi®) Empagliflozin/metformin (Synjardy®, Synjardy XR®) **CRITERIA FOR PRIOR AUTHORIZATION FOR SGLT2 INHIBITOR COMBINATIONS:** (must meet all of the following) • Patient must have a diagnosis of type II diabetes • Patient MUST NOT have a diagnosis of type I diabetes • Patient must be 18 years of age or older • Patient must have an eGFR above: o 45 mL/min/1.73m² (Glyxambi, Invokamet, Synjardy) o 60 mL/min/1.73m² (Xigduo XR) • Patient MUST NOT have any of the following contraindications: o End-stage renal disease o Currently on dialysis • Patient must have a trial of a preferred metformin ER agent at a maximum tolerated dose **LENGTH OF APPROVAL:** 12 months **Public Comment:** None. **Board Discussion:** None.	
C. Revised Prior Authorization (PA) Criteria 8. H.P. Acthar® (corticotropin) i. Revised PA Criteria	**Background:** H.P. Acthar is adrenocortical steroid. Prior authorization criteria were initially approved in July 2013. Step therapy and appropriate dosing is being proposed. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Dr. Heston moved to approve. Dr. Rice seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION

Initial Approval: July 10, 2013
Revised Dates: October 11, 2017

CRITERIA FOR PRIOR AUTHORIZATION

Repository Corticotropin Injection

PROVIDER GROUP Pharmacy
Professional

MANUAL GUIDELINES The following drug requires prior authorization:
Repository Corticotropin Injection (H.P. Acthar Gel®)

CRITERIA FOR INFANTILE SPASMS: (must meet all of the following)

- Patient has a diagnosis of infantile spasms
- Prescribed by or in consultation with a neurologist
- Patient is ≤ 2 years of age
- Prescribed daily dose does not exceed 75 U/m2 twice daily over 2 weeks with an additional 2 weeks of taper

CRITERIA FOR MULTIPLE SCLEROSIS: (must meet all of the following)

- Patient has a diagnosis of multiple sclerosis (MS)
- Prescribed by or in consultation with a neurologist
- Prescribed for an acute exacerbation of MS
- Inadequate response or significant intolerance/contraindication to injectable and oral corticosteroids
- Prescribed daily dose does not exceed 80-120 units daily (IM or SC injections) administered over 2 to 3 weeks

CRITERIA FOR RHEUMATIC DISORDERS: (must meet all of the following)

- Patient has one of the following diagnoses:
  - psoriatic arthritis
  - rheumatoid arthritis
  - juvenile rheumatoid arthritis
  - ankylosing spondylitis
- Prescribed by or in consultation with a rheumatologist
- Inadequate response or significant intolerance/contraindication to injectable and oral corticosteroids

CRITERIA FOR COLLAGEN DISEASES: (must meet all of the following)

- Patient has one of the following diagnoses:
  - systemic lupus erythematosus
  - systemic dermatomyositis (polymyositis)
- Prescribed by or in consultation with a rheumatologist
- Inadequate response or significant intolerance/contraindication to injectable and oral corticosteroids

CRITERIA FOR DERMATOLOGIC DISORDERS: (must meet all of the following)

- Patient has one of the following diagnoses:
  - erythma multiforme
  - Stevens-Johnson syndrome
- Prescribed by or in consultation with a dermatologist
- Inadequate response or significant intolerance/contraindication to injectable and oral corticosteroids

CRITERIA FOR ALLERGIC STATES: (must meet all of the following)

- Patient has a diagnosis of serum sickness
- Prescribed by or in consultation with an allergist or immunologist
- Inadequate response or significant intolerance/contraindication to injectable and oral corticosteroids

TOPIC	DISCUSSION	DECISION AND/OR ACTION

	CRITERIA FOR OPHTHALMIC DISEASES: (must meet all of the following)
	• Patient has one of the following diagnoses:
	  o keratosis
	  o iritis
	  o iridocyclitis
	  o diffuse posterior uveitis and choroiditis
	  o optic neuritis
	  o chorioretinitis
	  o anterior segment inflammation
	• Prescribed by or in consultation with an optometrist or ophthalmologist
	CRITERIA FOR RESPIRATORY DISEASES: (must meet all of the following)
	• Patient has a diagnosis of sarcoidosis
	• Prescribed by or in consultation with a pulmonologist
	CRITERIA FOR EDEMATOUS STATE: (must meet all of the following)
	• Patient has proteinuria in the nephritic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
	• Prescribed by or in consultation with a rheumatologist or nephrologist
	LENGTH OF APPROVAL Infantile spasms: 4 weeks (1 course)
	Multiple sclerosis: up to 3 weeks (1 course)
	All other indications: 1 month
	Notes:
	• Infantile spasms: Gradually taper over a 2-week period to avoid adrenal insufficiency. The following is one suggested tapering schedule: 30 units/m2 in the morning for 3 days; 15 units/m2 in the morning for 3 days; 10 units/m2 in the morning for 3 days; and 10 units/m2 every other morning for 6 days.
	• Multiple sclerosis: Treatment guidelines recommend the use of high dose IV or oral methylprednisolone for acute exacerbations of multiple sclerosis. Acthar 80 to 120 units IM or subcutaneously daily for 2 to 3 weeks for acute exacerbations
	Public Comment:
	None.
	Board Discussion:
	None.	

C. Revised Prior Authorization (PA) Criteria 9. Actemra® (tocilizumab) i. Revised PA Criteria	**Background:** Actemra is an interleukin-6 (IL-6) receptor antagonist. Prior authorization criteria were last revised in July 2017. Since that time, the medication has become indicated for the treatment of cytokine release syndrome (CRS). The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Dr. Heston moved to approve. Dr. Unruh seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION

Approved Date: April 14, 2010
Revised Dates: October 11, 2017; July 26, 2017; April 13, 2016
January 8, 2014; April 10, 2013; April 11, 2012

CRITERIA FOR PRIOR AUTHORIZATION

Actemra® (tocilizumab)

PROVIDER GROUP Professional

MANUAL GUIDELINES The following drug requires prior authorization:
Tocilizumab (Actemra®)

CRITERIA FOR RHEUMATOID ARTHRITIS (RA) (SUBQ & IV FORMULATIONS): (must meet all of the following)

- Patient must have a diagnosis of rheumatoid arthritis
- Must be prescribed by or in consultation with a rheumatologist
- Evaluation for latent tuberculosis (TB) with TB skin test prior to initial prior authorization approval
- Patient must be 18 years of age or older
- Patient has not taken another biologic agent (see attached table) in the past 30 days
- Must have documentation of inadequate response, contraindication, allergy, or intolerable side effects to at least one Disease-Modifying Anti-Rheumatic Drug (DMARD) (see attached table)
- Prior to initiation of therapy patient must have an absolute neutrophil count (ANC) ≥ 2,000 cells/mm^3
- Prior to initiation of therapy patient must have a platelet count ≥ 100,000 cells/mm^3
- Prior to initiation of therapy patient must have normal liver function tests (LFTs) (ALT or AST)
  - 1.5 times the upper limit of normal (ULN) is considered abnormal for tocilizumab therapy initiation
- IV formulation: Dose does not exceed 800 mg per IV infusion

RENEWAL CRITERIA FOR RA: (must meet initial criteria in addition to all of the following)

- Documentation of ANC, platelets and LFTs 4-8 weeks after initiation of therapy and then every 12 weeks
- Documentation of lipid parameters 4-8 weeks after initiation of therapy and then every 24 weeks
- IV formulation: Dose does not exceed 800 mg per IV infusion

CRITERIA FOR JUVENILE IDIOPATHIC ARTHRITIS (JIA) (IV FORMULATIONS ONLY): (must meet all of the following)

- Patient must have a diagnosis of juvenile idiopathic arthritis
- Must be prescribed by or in consultation with a rheumatologist
- Evaluation for latent TB with TB skin test prior to initial prior authorization approval
- Patient must be 2 years of age or older
- Patient has not taken another biologic agent (see attached table) in the past 30 days
- Prior to initiation of therapy patient must have an ANC ≥ 2,000 cells/mm^3
- Prior to initiation of therapy patient must have a platelet count ≥ 100,000 cells/mm^3
- Prior to initiation of therapy patient must have normal LFTs (ALT or AST)
  - 1.5 times the upper limit of normal (ULN) is considered abnormal for tocilizumab therapy initiation

RENEWAL CRITERIA FOR JIA: (must meet initial criteria in addition to all of the following)

- Documentation of ANC, platelets and LFTs 4-8 weeks after initiation of therapy and then every 12 weeks
- Documentation of lipid parameters 4-8 weeks after initiation of therapy and then every 24 weeks

CRITERIA FOR GIANT CELL ARTERITIS (GCA) (SUBQ FORMULATIONS ONLY): (must meet all of the following)

- Patient must have a diagnosis of giant cell arteritis (GCA)
- Must be prescribed by or in consultation with a rheumatologist
- Evaluation for latent TB with TB skin test prior to initial prior authorization approval
- Patient must be 18 years of age or older

TOPIC	DISCUSSION	DECISION AND/OR ACTION
C. Revised Prior Authorization (PA) Criteria 10. Darzalex® (daratumumab) i. Revised PA Criteria	**Background:** Darzalex is a CD38-directed cytolytic antibody. Prior authorization criteria were last revised in April 2017. Since that time, the medication has become indicated for the treatment of with multiple myeloma as combination therapy with pomalidomide and dexamethasone after at least 2 prior therapies including lenalidomide and a proteasome inhibitor. The prior authorization criteria are being revised to ensure appropriate used based upon the FDA-approved labeling information and be consistent with similar agents.	Ms. Dowd moved to approve. Dr. Heston seconded the motion. The criteria were approved unanimously.

Initial Approval: January 13, 2016
Revised Dates: October 11, 217; April 12, 2017

CRITERIA FOR PRIOR AUTHORIZATION

Darzalex® (daratumumab)

PROVIDER GROUP Professional

MANUAL GUIDELINES The following drug requires prior authorization:
Daratumumab (Darzalex)

CRITERIA FOR APPROVAL: (must meet all of the following)

- Patient must have a diagnosis of multiple myeloma (MM)
- Patient must meet one of the following:
  - When used as monotherapy, patient must have received at least 3 prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent, OR is double-refractory to a PI and an immunomodulatory agent
  - When used in combination with lenalidomide and dexamethasone, patient must have received at least 1 prior therapy
  - When used in combination with bortezomib and dexamethasone, patient must have received at least 1 prior therapy
  - When used in combination with pomalidomide and dexamethasone, patient must have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor
- Must be used in combination with a corticosteroid, antipyretic, and antihistamine
- Patient must be 18 years of age or older
- Must be prescribed by, or in consultation with, an oncologist or hematologist

LENGTH OF APPROVAL: 12 months

Notes:

- Recommended dose is 16 mg/kg actual body weight
  - Dosing schedule for monotherapy and in combination with lenalidomide (4-week cycle regimen)
    - Weeks 1-8: weekly (total of 8 doses). Weeks 9-24: every 2 weeks (total of 8 doses). Week 25 onwards until disease progression: every 4 weeks
  - Dosing schedule in combination with bortezomib (3-week cycle regimen)
    - Weeks 1-9: weekly (total of 9 doses). Weeks 10-24: every 3 weeks (total of 5 doses). Week 25 onwards until disease progression: every 4 weeks

Public Comment:
None.
Board Discussion:

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Criteria that noted 'Must be given in a medical setting or a hospital setting' had been removed due to the level of confusion it caused per a previous discussion.	
C. Revised Prior Authorization (PA) Criteria 11. Imbruvica® (ibrutinib) i. Revised PA Criteria	**Background:** Imbruvica is a kinase inhibitor. Prior authorization criteria were last revised in April 2017. Since that time, the medication has become indicated for the treatment of chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. Initial Approval: October 14, 2015 Revised Dates: October 11, 2017; April 12, 2017 July 13, 2016; April 13, 2016 CRITERIA FOR PRIOR AUTHORIZATION Imbruvica® (ibrutinib) PROVIDER GROUP: Pharmacy MANUAL GUIDELINES: The following drug requires prior authorization: Ibrutinib (Imbruvica®) CRITERIA FOR INITIAL APPROVAL (must meet all of the following): • Patient must be clinically diagnosed with one of the following diagnoses: o Chronic lymphoid leukemia (CLL) o Small lymphocytic lymphoma (SLL) o Chronic lymphoid leukemia (CLL) with 17p chromosome deletion o Small lymphocytic lymphoma (SLL) with 17p chromosome deletion o Mantle cell lymphoma (MCL) ▪ Patient has received at least one prior therapy o Waldenström macroglobulinemia o Marginal zone lymphoma (MZL) in those who require systemic therapy ▪ Patient has received at least one prior anti-CD20-based therapy o Chronic graft versus host disease (cGVHD) ▪ Patient has had a failure of one or more lines of systemic therapy • The medication is prescribed by or in consultation with an oncologist or hematologist • Patient must not be pregnant LENGTH OF APPROVAL: 6 months CRITERIA FOR RENEWAL (must meet all of the following): • Must meet initial criteria for renewal RENEWAL LENGTH OF APPROVAL: 12 months Notes: • Refer to most recent NCCN (National Comprehensive Cancer Network) Guidelines for NCCN accepted regimens. • Anti-CD20 (although, not all may be indicated for the diagnosis): Rituximab, ibritumomab, obinutuzumab, ofatumumab **Public Comment:** None.	Ms. Dowd moved to approve. Dr. Rice seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Board Discussion: None.	
C. Revised Prior Authorization (PA) Criteria 12. Mekinist® (trametinib) i. Revised PA Criteria	**Background:** Mekinist is a kinase inhibitor. Prior authorization criteria were last revised in April 2014. Since that time, the medication has become indicated for the treatment of metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation in combination with dabrafenib. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Dr. Rice moved to approve as written. Ms. Dowd seconded the motion. The criteria were approved unanimously.

Initial Approval: October 9, 2013
Revised Date: October 11, 2017; April 9, 2014

CRITERIA FOR PRIOR AUTHORIZATION

Mekinist® (trametinib)

PROVIDER GROUP: Pharmacy

MANUAL GUIDELINES: The following drug requires prior authorization:
Trametinib (Mekinist®)

CRITERIA FOR TRAMETINIB (Must meet all of the following):

- Patient must meet one of the following:
  - Patient must have a diagnosis of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation
    - When used as a single agent, patient must not have received previous treatment with a BRAF-inhibitor
    - When used as combination therapy, must be used with dabrafenib
  - Patient must have a diagnosis of metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation
    - Must be used with dabrafenib
- Patient must not be pregnant or breastfeeding and be advised to not become pregnant for at least 4 months after the final dose
- Prescribed by or in consultation with an oncologist or hematologist

LENGTH OF APPROVAL: 12 months

	Public Comment: None. **Board Discussion:** None.	
C. Revised Prior Authorization (PA) Criteria 13. Opdivo® (nivolumab) i. Revised PA Criteria	**Background:** Opdivo is a programmed death receptor-1 (PD-1) blocking antibody. Prior authorization criteria were last revised in April 2017. Since that time, the medication has become indicated for the treatment of adult and pediatric (12 years and older) patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.	Dr. Unruh moved to approve. Ms. Dowd seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. Initial Approval: October 14, 2015 Revised Dates: October 11, 2017; April 12, 2017 October 12, 2016; April 13, 2016 CRITERIA FOR PRIOR AUTHORIZATION Opdivo® (nivolumab) PROVIDER GROUP: Pharmacy MANUAL GUIDELINES: The following drug requires prior authorization: Nivolumab (Opdivo®) CRITERIA FOR APPROVAL (must meet all of the following): • Patient must have one of the following diagnoses: o Unresectable or metastatic melanoma ▪ Medication must be used as a single agent or in combination with ipilimumab o Metastatic non-small cell lung cancer (NSCLC) with disease progression on or after platinum-based chemotherapy ▪ If EGFR or ALK mutation present, patient must have failure with a mutation specific medication prior to using Opdivo o Advanced renal cell carcinoma ▪ Patient must have received prior anti-angiogenic therapy o Classical Hodgkin lymphoma that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation brentuximab vedotin o Recurrent or metastatic squamous cell carcinoma of the head and neck (HNSCC) with disease progression on or after platinum-based chemotherapy o Locally advanced or metastatic urothelial carcinoma who: ▪ Have disease progression during or following platinum-containing chemotherapy ▪ Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy o Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer ▪ Must be 12 years of age or older ▪ Has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan • Must be prescribed by or in consultation with an oncologist • Patient must be 18 years of age or older LENGTH OF APPROVAL: 12 months **Public Comment:** None. **Board Discussion:** Ms. Grant noted that the State, having a limited Medicaid budget, is working to address the influx of specialty drugs and being able to care for patients.	
C. Revised Prior Authorization (PA) Criteria	**Background:** Orencia is a T cell costimulation modulator. Prior authorization criteria were last revised in April 2016. Since that time, the medication has become indicated for the treatment of adult	Ms. Dowd moved to approve. Dr. Unruh seconded the motion.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
14. Orencia® (abatacept) i. Revised PA Criteria	psoriatic arthritis (PsA). The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	The criteria were approved unanimously.

Initial Approval: November 1, 2016
Revised Dates: October 11, 2017; April 13, 2016
April 11, 2012; November 12, 2008; July 9, 2008

CRITERIA FOR PRIOR AUTHORIZATION

Orencia® (abatacept)

PROVIDER GROUP Pharmacy
Professional

MANUAL GUIDELINES The following drug requires prior authorization:
Abatacept (Orencia®)

CRITERIA FOR RHEUMATOID ARTHRITIS (RA): (must meet all of the following)

- Patient must have a diagnosis of rheumatoid arthritis
- Must be prescribed by or in consultation with a rheumatologist
- Evaluation for latent tuberculosis (TB) with TB skin test prior to initial prior authorization approval
- Patient must be 18 years of age or older
- Patient has not taken another biologic agent (see attached table) in the past 30 days

CRITERIA FOR JUVENILE IDIOPATHIC ARTHRITIS (JIA): (must meet all of the following)

- Patient must have a diagnosis of juvenile idiopathic arthritis
- Must be prescribed by or in consultation with a rheumatologist
- Evaluation for latent TB with TB skin test prior to initial prior authorization approval
- Patient must be 2 years of age or older
- Patient has not taken another biologic agent (see attached table) in the past 30 days

CRITERIA FOR PSORIATIC ARTHRITIS (PSA): (must meet all of the following)

- Patient must have a diagnosis of psoriatic arthritis
- Must be prescribed by or in consultation with a rheumatologist or dermatologist
- Evaluation for latent TB with TB skin test prior to initial prior authorization approval
- Patient must be 18 years of age or older
- Patient has not taken another biologic agent (see attached table) in the past 30 days

LENGTH OF APPROVAL: 12 months

Public Comment:
None.
Board Discussion:
None.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
C. Revised Prior Authorization (PA) Criteria 15. Lynparza® (olaparib) i. Revised PA Criteria	**Background:** Lynparza is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer and for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer. Prior authorization criteria were initially approved in July 2017. A new formulation (tablet) has been approved that have additional indications than the capsule. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Dr. Heston moved to approve. Ms. Dowd seconded the motion. The criteria were approved unanimously.

Initial Approval: July 26, 2017
Revised Date: October 11, 2017

CRITERIA FOR PRIOR AUTHORIZATION

Lynparza™ (olaparib)

PROVIDER GROUP: Pharmacy

MANUAL GUIDELINES: The following drug requires prior authorization:
Olaparib (Lynparza™)

CRITERIA FOR APPROVAL (must meet all of the following):

- Patient must have one of the following:
  - Diagnosis of advanced ovarian cancer (tablets or capsules)
    - Patient must have a deleterious or suspected deleterious germline BRCA-mutation (as detected by an approved test)
    - Patient must have been treated with 3 or more prior lines of chemotherapy
  - Diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer for maintenance therapy (tablets only)
    - Patient must be in a complete or partial response to platinum-based chemotherapy
- Must be prescribed by or in consultation with an oncologist
- Patient must be 18 years of age or older
- Patient must not be pregnant or breastfeeding and be advised to not become pregnant for at least 1 month after the last dose
- Patient must be taking olaparib as monotherapy

LENGTH OF APPROVAL: 12 months

Notes:

- For capsules: The recommended dose is 400 mg (eight 50 mg capsules) taken twice daily, for a total daily dose of 800 mg. Continue treatment until disease progression or unacceptable toxicity.
- For tablets: The recommended dose is 300 mg taken orally twice daily. Continue treatment until disease progression or unacceptable toxicity.
- Do not substitute Lynparza tablets with Lynparza capsules on a milligram-to-milligram basis due to differences in the dosing and bioavailability of each formulation

Public Comment:
None.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Board Discussion: None.	
C. Revised Prior Authorization (PA) Criteria 16. Trokendi XR® (topiramate extended-release) i. Revised PA Criteria	**Background:** Trokendi is an anticonvulsant. Prior authorization criteria were initially approved in January 2014. Since that time, the medication has become indicated for the prophylaxis of migraine headache in adults and adolescents 12 years of age and older and as monotherapy in those with partial onset seizures or primary generalized tonic-clonic seizures in those who are at least 6 years of age. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents. Initial Approval: January 8, 2014 Revised Date: October 11, 2017 CRITERIA FOR PRIOR AUTHORIZATION Trokendi XR® (topiramate extended-release) PROVIDER GROUP: Pharmacy MANUAL GUIDELINES: The following drug requires prior authorization: topiramate extended-release (Trokendi XR) CRITERIA FOR LENNOX-GASTAUT SYNDROME (LGS): (must meet all of the following) • Patient must have seizures associated with a diagnosis of Lennox-Gastaut Syndrome • Must be using as adjunctive therapy • Patient must be 6 years of age or older • Must be prescribed by or in consultation with a neurologist CRITERIA FOR PARTIAL ONSET OR PRIMARY GENERALIZED TONIC-CLONIC SEIZURES: (must meet all of the following) • Patient must have a diagnosis of partial onset or primary generalized tonic-clonic seizures • Patient must be 6 years of age or older • Must be prescribed by or in consultation with a neurologist CRITERIA FOR MIGRAINE PROPHYLAXIS: (must meet all of the following) • Patient must have a diagnosis of migraine headaches • Patient must be 12 years of age or older • Patient has had a trial of topiramate IR • Must be prescribed by or in consultation with a neurologist • Dose does not exceed 100 mg LENGTH OF APPROVAL: 12 months **Public Comment:** None. **Board Discussion:** None.	Dr. Heston moved to approve. Ms. Dowd seconded the motion. The criteria were approved unanimously.
C. Revised Prior Authorization (PA) Criteria 17. Daklinza® (daclatasvir)	**Background:** Daklinza is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in January 2017. There is a black box	Ms. Dowd moved to approve. Dr. Rice seconded the motion.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
i. Revised PA Criteria	warning for the risk of hepatitis B reactivation. With new agents approved for other genotypes, consistent wording for using the preferred agent is being added. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	The criteria were approved unanimously.

Initial Approval: October 14, 2015
Revised Dates: October 11, 2017; January 11, 2017
April 13, 2016

CRITERIA FOR PRIOR AUTHORIZATION

Daklinza® (daclatasvir)

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Daclatasvir (Daklinza®)

CRITERIA FOR INITIAL APPROVAL OF DACLATASVIR: (must meet all of the following):
Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 12 weeks of daclatasvir therapy total)

- Patient must have a diagnosis of chronic hepatitis C (CHC)
- Patient must have genotype 1 or 3 hepatitis C
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Must be used in combination with Sovaldi® (sofosbuvir)
- Patient must not have been on a previous or concurrent direct acting hepatitis C agent (except concurrent therapy with Sovaldi® according to acceptable treatment therapy options)
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request
- Dose must not exceed 1 tablet per day
- Patient must have a Metavir score of F3 or greater
- Patient must not be concurrently prescribed a strong CYP3A inducer (e.g. phenytoin, carbamazepine, rifampin, St. John's wort)
- Patient must not be on concurrent moderate CYP3A inducers (e.g. bosentan, dexamethasone, efavirenz, etravirine, modafinil, nafcillin, rifapentine)
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with daclatasvir combination therapy
- For all genotypes: the PDL preferred drug, which covers that specific genotype, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines
- Patient must be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment

CRITERIA FOR RENEWAL (must meet all of the following):

- Prescriber must document adherence by patient of greater than or equal to 90% for both agents

LENGTH OF APPROVAL: 4 weeks for a **total of 12 weeks of treatment**

Public Comment:
None.
Board Discussion:
None.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
C. Revised Prior Authorization (PA) Criteria 18. Epclusa® (sofosbuvir/velpatasvir) i. Revised PA Criteria	**<u>Background:</u>** Epclusa is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in January 2017. There is a black box warning for the risk of hepatitis B reactivation. With new agents approved for other genotypes, consistent wording for using the preferred agent is being added. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Ms. Dowd moved to approve. Dr. Heston seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION

Initial Approval: July 13, 2016
Revised Dates: October 11, 2017; January 11, 2017

CRITERIA FOR PRIOR AUTHORIZATION

Epclusa® (sofosbuvir/velpatasvir)

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Sofosbuvir/Velpatasvir (Epclusa®)

CRITERIA FOR INITIAL APPROVAL OF SOFOSBUVIR/VELPATASVIR: (must meet all of the following)

Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 12 weeks of Sofosbuvir/Velpatasvir therapy total)

- Patient must have a diagnosis of chronic hepatitis C (CHC)
- Patient must have genotype 1, 2, 3, 4, 5, or 6 hepatitis C
- Patient must not have severe renal impairment (eGFR<30mL/min/1.73m²) or currently require hemodialysis
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Patient must not have been on previous or concurrent direct acting hepatitis C agents
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request
- Dose must not exceed 1 tablet per day
- Patient must have one of the following:
  - Advanced fibrosis (as defined by a Metavir score of F3)
  - Cirrhosis
  - Organ transplant
  - Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis)
  - Proteinuria
  - Nephrotic syndrome
  - Membranoproliferative glomerulonephritis
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with sofosbuvir/velpatasvir therapy
- If the patient has decompensated cirrhosis, sofosbuvir/velpatasvir must be used in combination with ribavirin
- If the patient has compensated cirrhosis, sofosbuvir/velpatasvir must *not* be used in combination with ribavirin
- Patient must not be on concurrent:
  - Amiodarone
  - Moderate to strong inducers of CYP2B6 (e.g., carbamazepine, fosphenytoin, nevirapine, phenobarbital, phenytoin, primidone, rifampin)
  - Moderate to strong inducers of CYP2C8 (e.g., rifampin)
  - Moderate to strong inducers of CYP3A4 (e.g., avasimibe, carbamazepine, dexamethasone, ethosuximide, griseofulvin, phenytoin, primidone, progesterone, rifabutin, rifampin, nafcillin, nelfinavir, nevirapine, oxcarbazepine, phenobarbital, phenylbutazone, St John's wort, sulfadimidine, sulfinpyrazone, troglitazone)
  - Inducers of P-gp (e.g., avasimibe, carbamazepine, phenytoin, rifampin, St John's wort, tipranavir/ritonavir)
- For all genotypes: the PDL preferred drug, which covers that specific genotype, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	• Patient must be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment RENEWAL CRITERIA FOR SOFOSBUVIR/VELPATASVIR: • Prescriber must document adherence by patient of greater than or equal to 90% LENGTH OF APPROVAL FOR SOFOSBUVIR/VELPATASVIR: 4 weeks for a **total of 12 weeks of treatment** Notes: • No patients with genotype 5 were enrolled in the trial to determine decompensated cirrhosis outcomes. • Treatment with Epclusa with ribavirin in patients with decompensated cirrhosis for 12 weeks resulted in numerically higher SVR12 rates than treatment of Epclusa alone for 12 weeks for 24 weeks. **Public Comment:** None. **Board Discussion:** None.	
C. Revised Prior Authorization (PA) Criteria 19. Board Discussion on combining original Agenda Items 19 through 23 for the purpose of voting i. Revised PA Criteria	**Board Discussion:** The Board noting that the same change is being made in the original Agenda items 19 through 23 would combine these items for the purpose of voting. Each Item would be called and public comment requested but only one vote to approve/reject the items would be made.	Dr. Heston moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously.
C. Revised Prior Authorization (PA) Criteria 20. (Original Agenda Item 19) Zepatier® (elbasvir/grazoprevir) i. Revised PA Criteria	**Background:** Zepatier is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in April 2017. There is a black box warning for the risk of hepatitis B reactivation. With new agents approved for other genotypes, consistent wording for using the preferred agent is being added. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Dr. Unruh moved to approve original Agenda Items 19 through 23. Ms. Dowd seconded the motion. All criteria for the original Agenda Items 19 through 23

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Initial Approval: April 13, 2016 Revised Dates: October 11, 2017; April 12, 2017 January 11, 2017 **CRITERIA FOR PRIOR AUTHORIZATION** Zepatier® (elbasvir/grazoprevir) **PROVIDER GROUP** Pharmacy **MANUAL GUIDELINES** The following drug requires prior authorization: Elbasvir/Grazoprevir (Zepatier®) **CRITERIA FOR INITIAL APPROVAL** (must meet all of the following): **Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 12 weeks of elbasvir/grazoprevir therapy total for most patients or 16 weeks for genotype 1a with baseline polymorphisms or genotype 4 IFN/RBV-experienced)** • Patient must have a diagnosis of chronic hepatitis C (CHC) • Patient must have genotype 1 or 4 hepatitis C • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • Patient must be 18 years of age or older • Patient must not have been on previous or concurrent direct acting hepatitis C agent • Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months • Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request • Dose must not exceed 1 tablet per day • Patient must have one of the following: o Advanced fibrosis (Metavir F3 or greater) o Compensated cirrhosis o Organ transplant o Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis) o Proteinuria o Nephrotic syndrome o Membranoproliferative glomerulonephritis • Patient must not have moderate or severe hepatic impairment (Child-Pugh class B or C) • Female patients on concurrent ribavirin must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during elbasvir/grazoprevir treatment • Patient must not be concurrently prescribed a strong CYP3A inducer, efavirenz, or OATP1B1/3 inhibitor • If the patient has genotype 1a, patient must be tested for the presence of virus with NS5A resistance-associated polymorphisms prior to initiation of therapy • For all genotypes: the PDL preferred drug, which covers that specific genotype, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines • Patient must be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment **CRITERIA FOR RENEWAL** (must meet all of the following): • Prescriber must document adherence by patient of greater than or equal to 90% for both agents	were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	LENGTH OF APPROVAL: 4 weeks for a **total of 12 weeks of treatment** 4 weeks for a **total of 16 weeks of treatment** for patients with one of the following: • Genotype 1a with baseline NS5A polymorphisms • Genotype 4 and Peg-Interferon/ribavirin experienced Notes: • OATP1B1 inhibitors include (but not limited to): cyclosporine, eltrombopag, lapatinib, lopinavir, rifampin, ritonavir • OATP1B3 inhibitors include (but not limited to): cyclosporine, lopinavir, rifampin, ritonavir • Strong CYP3A inducers include (but not limited to): phenytoin, carbamazepine, rifampin, St. John's wort **Public Comment:** None. **Board Discussion:** None.	
C. Revised Prior Authorization (PA) Criteria 21. (Original Agenda Item 20) Olysio® (simeprevir) i. Revised PA Criteria	**Background:** Olysio is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in January 2017. There is a black box warning for the risk of hepatitis B reactivation. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	

TOPIC	DISCUSSION	DECISION AND/OR ACTION

Initial Approval: January 8, 2014
Revised Date: October 11, 2017; January 11, 2017; October 14, 2015
July 8, 2015; April 8, 2015; July 9, 2014; April 9, 2014

CRITERIA FOR PRIOR AUTHORIZATION

Direct Acting Hepatitis C Agents

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Simeprevir (Olysio®)

CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF ONE DIRECT ACTING AGENT: (must meet all of the following)

Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of 12 weeks of Olysio therapy total)

- Patient must have a diagnosis of chronic hepatitis C (CHC)
- Patient must have genotype 1 hepatitis C
- If patient has subtype 1a they must have a negative test for NS3-Q80k polymorphism
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Olysio must be used in combination with Peginterferon alfa and ribavirin or sofosbuvir
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Olysio
- Patient must not have been on a previous or concurrent direct acting hepatitis C agent
- Dose must not exceed 1 capsule per day
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- The patient must not have advanced and/or decompensated cirrhosis (moderate or severe hepatic impairment)
- Patient must have one of the following:
  - Advanced fibrosis (as defined by a Metavir score of F3)
  - Compensated cirrhosis
  - Organ transplant
  - Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (e.g., vasculitis)
  - Proteinuria
  - Nephrotic syndrome
  - Membranoproliferative glomerulonephritis
- For all genotypes: the PDL preferred drug, which covers that specific genotype, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines
- Patient must be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment

LENGTH OF INITIAL APPROVAL FOR ONE DIRECT ACTING AGENT 12 weeks

Ribavirin and peg-interferon alfa are approved when using triple therapy with Olysio, if Olysio criteria are met.

DISCONTINUATION CRITERIA FOR ONE DIRECT ACTING AGENT

- Provider must submit HCV RNA level after treatment week 4, within 7 days, to prevent discontinuation of therapy
- Therapy will be discontinued if the HCV RNA level is greater than or equal to 25IU/mL after treatment week 4

CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF TWO DIRECT ACTING AGENTS: (must meet all of the following)

- Patient must have a diagnosis of chronic hepatitis C (CHC) genotype 1
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

TOPIC	DISCUSSION	DECISION AND/OR ACTION
C. Revised Prior Authorization (PA) Criteria 22. (Original Agenda Item 21) Viekira®, Viekira XR® (ombitasvir/paritaprevir/ritonavir/dasabuvir) i. Revised PA Criteria	**Background:** Viekira is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in January 2017. There is a black box warning for the risk of hepatitis B reactivation. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	

Initial Approval: January 14, 2015
Revised Dates: October 11, 2017; January 11, 2017; October 12, 2016; January 13, 2016; October 14, 2015

CRITERIA FOR PRIOR AUTHORIZATION

Direct Acting Hepatitis C Agent

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Ombitasvir/paritaprevir/ritonavir and dasabuvir (Viekira Pak™, Viekira XR®)

CRITERIA FOR INITIAL APPROVAL: (must meet all of the following)

Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 24 weeks of Viekira Pak therapy total)

- Patient must have a diagnosis of chronic hepatitis C (CHC)
- Patient must have genotype 1 hepatitis C
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Must be used in combination with ribavirin unless patient has genotype 1b
- Patient must not have been on a previous or concurrent direct acting hepatitis C agent
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Dose must not exceed 1 daily dose pack per day (Viekira Pak: 2 ombitasvir/paritaprevir/ritonavir and 2 dasabuvir tablets per day; Viekira XR: 3 ombitasvir/paritaprevir/ritonavir/dasabuvir tablets per day)
- Patient must not have underlying moderate to severe hepatic impairment (Child-Pugh class B or C)
- Patient must have one of the following:
  - Advanced fibrosis (Metavir F3)
  - Compensated cirrhosis
  - Organ transplant
  - Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis)
  - Proteinuria
  - Nephrotic syndrome
  - Membranoproliferative glomerulonephritis
- For all genotypes: the PDL preferred drug, which covers that specific genotype, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines
- Patient must be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment

RENEWAL CRITERIA:

- Prescriber must document adherence by patient of greater than or equal to 90% and meet one of the following:
  - Genotype 1a with cirrhosis or mixed genotype with cirrhosis – **up to 24 weeks total therapy**
  - Liver transplant recipient with normal hepatic function and mild fibrosis (Metavir fibrosis score 2 or lower) – **24 weeks total therapy**
  - Genotype 1a without cirrhosis, mixed genotype without cirrhosis or genotype 1b with or without cirrhosis – **12 weeks total therapy**

LENGTH OF APPROVAL FOR VIEKIRA PAK: 4 weeks

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Public Comment: None. **Board Discussion:** None.	
C. Revised Prior Authorization (PA) Criteria 23. (Original Agenda Item 22) Harvoni® (ledipasvir/sofosbuvir) i. Revised PA Criteria	**Background:** Harvoni is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in July 2017. With new agents approved for other genotypes, consistent wording for using the preferred agent is being added. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	

TOPIC	DISCUSSION	DECISION AND/OR ACTION

Initial Approval: November 14, 2014
Revised Dates: July 26, 2017; January 11, 2017; April 13, 2016
January 13, 2016; October 14, 2015; January 14, 2015

CRITERIA FOR PRIOR AUTHORIZATION

Fixed Combination Direct Acting Hepatitis C Agent

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Ledipasvir/Sofosbuvir (Harvoni®)

CRITERIA FOR INITIAL APPROVAL OF LEDIPASVIR/SOFOSBUVIR: (must meet all of the following)

Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 24 weeks of Ledipasvir/Sofosbuvir therapy total)

- Patient must have a diagnosis of chronic hepatitis C virus (HCV)
- Patient must have genotype 1, 4, 5, or 6 hepatitis C
- Patient must not have severe renal impairment (eGFR<30mL/min/1.73m^2) or currently require hemodialysis
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be at least 12 years of age or weighing at least 35 kg
- Patient must not have been on previous or concurrent direct acting hepatitis C agents
- If patient was on a previous course of treatment with Incivek or Victrelis it must have included an interferon-based regimen
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request
- Dose must not exceed 1 tablet per day
- Patient must have one of the following:
  - Advanced fibrosis (Metavir F3)
  - Compensated cirrhosis
  - Organ transplant
  - Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis)
  - Proteinuria
  - Nephrotic syndrome
  - Membranoproliferative glomerulonephritis
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with ledipasvir/sofosbuvir therapy
- For all genotypes: the PDL preferred drug, which covers that specific genotype, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines
- Patient must be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment
- Coadministration with amiodarone is not recommended. If alternative, viable treatment options are unavailable, cardiac monitoring is recommended

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	RENEWAL CRITERIA FOR LEDIPASVIR/SOFOSBUVIR: • Prescriber must document adherence by patient of greater than or equal to 90% • Must meet one of the following: o **Genotype 1 (one of the following)** ▪ Treatment-naïve, without cirrhosis, and a pre-treatment HCV RNA < 6 million IU/mL – **8 weeks total therapy** ▪ Treatment-naïve, with or without cirrhosis, and a pre-treatment HCV RNA ≥ 6 million IU/mL – **12 weeks total therapy** ▪ Treatment-naïve, with cirrhosis– **12 weeks total therapy** ▪ Treatment-experienced, without cirrhosis – **12 weeks total therapy** ▪ Treatment-experienced, with cirrhosis: • **24 weeks total therapy alone** • **12 weeks total therapy if used with Ribavirin** ▪ Decompensated cirrhosis (Child-Pugh B or C) – **12 weeks total therapy with ribavirin** ▪ Post-liver transplant, in those who are treatment-naïve or experienced, without cirrhosis or with compensated cirrhosis – **12 weeks total therapy with ribavirin** o **Genotype 4** ▪ Treatment-naïve and treatment- experienced, without cirrhosis or with compensated cirrhosis (Child-Pugh A) – **12 weeks total therapy** ▪ Post-liver transplant, in those who are treatment-naïve or experienced, without cirrhosis or with compensated cirrhosis – **12 weeks total therapy with ribavirin** o **Genotype 5 or 6** ▪ Treatment-naïve and treatment- experienced, without cirrhosis or with compensated cirrhosis (Child-Pugh A) – **12 weeks total therapy** **LENGTH OF APPROVAL FOR LEDIPASVIR/SOFOSBUVIR:** 4 weeks **Public Comment:** None. **Board Discussion:** None.	
C. Revised Prior Authorization (PA) Criteria 24. (Original Agenda Item 23) Sovaldi® (sofosbuvir) i. Revised PA Criteria	**Background:** Sovaldi is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were last revised in April 2017. With new agents approved for other genotypes, consistent wording for using the preferred agent is being added. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	

TOPIC	DISCUSSION	DECISION AND/OR ACTION

Initial Approval: January 8, 2014
Revised Dates: October 11, 2017; July 26, 2017; April 12, 2017; January 11, 2017; October 14, 2015; April 8, 2015; July 9, 2014; April 9, 2014

CRITERIA FOR PRIOR AUTHORIZATION

Direct Acting Hepatitis C Agent

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Sofosbuvir (Sovaldi®)

CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF ONE DIRECT ACTING AGENT: (must meet all of the following)

Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of 48 weeks of Sovaldi therapy total)

- Patient must have a diagnosis of chronic hepatitis C virus (HCV)
- Patient must have genotype 1, 2, 3, or 4 hepatitis C
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older for genotype 1 or 4
- Patient must be at least 12 years of age or weighing at least 35 kg (77 lbs) for genotype 2 or 3
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Sovaldi
- Patient must not have been on previous or concurrent direct acting hepatitis C agents
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Dose must not exceed 1 tablet per day
- Patient must have one of the following:
  - Advanced fibrosis (as defined by a Metavir score of F3)
  - Compensated cirrhosis
  - Organ transplant
  - Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (e.g., vasculitis)
  - Proteinuria
  - Nephrotic syndrome
  - Membranoproliferative glomerulonephritis
- For all genotypes: the PDL preferred drug, which covers that specific genotype, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines
- Patient must be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment
- Coadministration with amiodarone is not recommended. If alternative, viable treatment options are unavailable, cardiac monitoring is recommended

LENGTH OF INITIAL APPROVAL FOR ONE DIRECT ACTING AGENT 12 weeks

Ribavirin and Peginterferon alfa are approved when using triple therapy with Sovaldi, if Sovaldi criteria are met.

RENEWAL CRITERIA FOR ONE DIRECT ACTING AGENT: (must meet one of the following)

- Patient is infected with genotype 3 HCV (an additional 12 weeks of therapy will be approved for a max of 24 weeks if the patient is on an interferon-free regimen; Sovaldi plus ribavirin and interferon will only be approved for a max of 12 weeks.)

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	• Patient is infected with genotype 1 HCV and is ineligible to receive interferon-based therapy (an additional 12 weeks of therapy will be approved for a max of 24 weeks) • Patient has a diagnosis of hepatocellular carcinoma (HCC) and is awaiting a liver transplantation (an additional 36 weeks of therapy will be approved for a max of 48 weeks) CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF SOVALDI PLUS OLYSIO: (must meet all of the following) • Patient must have a diagnosis of chronic hepatitis C virus (HCV) genotype 1 • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • Patient must be 18 years of age or older • Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Sovaldi • Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months • Dose must not exceed 1 tablet per day • Patient must not have been on previous or concurrent direct acting hepatitis C agents • Patient must have one of the following: o Advanced fibrosis (as defined by a Metavir score of F3) o Compensated cirrhosis o Organ transplant o Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (e.g., vasculitis) o Proteinuria o Nephrotic syndrome o Membranoproliferative glomerulonephritis • Patient must not be on previous or concurrent therapy with Olysio unless the patient is interferon ineligible defined as one or more of the following: o Documented intolerance to IFN o Autoimmune hepatitis or other autoimmune disorder o Documented hypersensitivity to PEG or any of its components o Decompensated hepatic disease o Major uncontrolled depressive illness o A baseline neutrophil count below 1500 a baseline platelet count below 90,000 or baseline hemoglobin below 10 g/dL o A history of preexisting cardiac disease • For all genotypes: the PDL preferred drug, which covers that specific genotype, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines • Patient must be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment • Coadministration with amiodarone is not recommended. If alternative, viable treatment options are unavailable, cardiac monitoring is recommended LENGTH OF INITIAL APPROVAL 4 weeks RENEWAL CRITERIA FOR SOVALDI PLUS OLYSIO: (must the following) • Prescriber must document adherence by patient of greater than or equal to 90% for both agents LENGTH OF RENEWAL 4 weeks for a **total of 12 weeks of treatment**	

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF SOVALDI PLUS DAKLINZA: (must meet all of the following) • Patient must have a diagnosis of chronic hepatitis C virus (HCV) genotype 3 • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist • Patient must be 18 years of age or older • Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Sovaldi • Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months • Dose must not exceed 1 tablet per day • Patient must not have been on previous or concurrent direct acting hepatitis C agents • Patient must have one of the following: o Metavir score of F3 or greater o Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (e.g., vasculitis) o Proteinuria o Nephrotic syndrome o Membranoproliferative glomerulonephritis o Organ transplant • Patient must be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment • Coadministration with amiodarone is not recommended. If alternative, viable treatment options are unavailable, cardiac monitoring is recommended **LENGTH OF INITIAL APPROVAL** 4 weeks **RENEWAL CRITERIA FOR SOVALDI PLUS DAKLINZA:** (must the following) • Prescriber must document adherence by patient of greater than or equal to 90% for both agents **LENGTH OF RENEWAL** 4 weeks for a **total of 12 weeks of treatment** **Public Comment:** None. **Board Discussion:** None.	
C. Revised Prior Authorization (PA) Criteria 25. (Original Agenda Item 24) Vosevi® (sofosbuvir/velpatasvir/voxilaprevir) i. Revised PA Criteria	**Background:** Vosevi is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). Prior authorization criteria were initially approved in July 2017. With new agents approved for other genotypes, consistent wording for using the preferred agent is being added. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Dr. Heston moved to approve. Ms. Dowd seconded the motion. The criteria were approved unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION

Initial Approval: July 26, 2017
Revised Dates: October 11, 2017

CRITERIA FOR PRIOR AUTHORIZATION

Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir)

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi™)

CRITERIA FOR INITIAL APPROVAL OF SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR: (must meet all of the following)

Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 12 weeks of Sofosbuvir/Velpatasvir/Voxilaprevir therapy total)

- Patient must have a diagnosis of chronic hepatitis C (CHC) (hepatitis C virus [HCV])
- Patient must have genotype 1, 2, 3, 4, 5, or 6 hepatitis C
- Patient must not have severe renal impairment (eGFR<30mL/min/1.73m²) or currently require hemodialysis
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Patient must not be on concurrent direct acting hepatitis C agents
- Patient must meet one of the following:
  - Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor
  - Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir WITHOUT an NS5A inhibitor
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request
- Dose must not exceed 1 tablet per day
- Patient must have one of the following:
  - Advanced fibrosis (Metavir F3)
  - Compensated cirrhosis (Child-Pugh A)
  - Organ transplant
  - Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis)
  - Proteinuria
  - Nephrotic syndrome
  - Membranoproliferative glomerulonephritis
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with sofosbuvir/velpatasvir/voxilaprevir therapy
- For all genotypes: the PDL preferred drug, which covers that specific genotype, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines
- Patient must be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment
- Patient must not be on concurrent rifampin
- Patient should not be on concurrent:
  - P-gp inducers
  - Moderate to potent CYP2B6, 2C8, or 3A4 inducers
  - Amiodarone (if alternative, viable treatment options are unavailable, cardiac monitoring is recommended)

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	RENEWAL CRITERIA FOR SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR: • Prescriber must document adherence by patient of greater than or equal to 90% LENGTH OF APPROVAL FOR SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR: 4 weeks for a **total of 12 weeks of treatment** Notes: • NS5A inhibitors: daclatasvir, elbatasvir, ledipasvir, ombitasvir, velpatasvir • Additional benefit of Vosevi over sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor. **Public Comment:** None. **Board Discussion:** None.	
D. New Prior Authorization (PA) Criteria 1. Mavyret® (glecaprevir/pibrentasvir) i. Prior Authorization Criteria	**Background:** Mavyret is a direct acting antiviral agent indicated for the treatment of hepatitis C virus (HCV). The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Dr. Heston moved to approve as amended. Ms. Dowd seconded the motion. The criteria were approved as amended unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION

Initial Approval: October 11, 2017

CRITERIA FOR PRIOR AUTHORIZATION

Mavyret™ (glecaprevir/pibrentasvir)

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Glecaprevir/Pibrentasvir (Mavyret™)

CRITERIA FOR INITIAL APPROVAL (must meet all of the following):
Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to the duration listed below)

- Patient must have a diagnosis of chronic hepatitis C virus (HCV)
- Patient must have genotype 1, 2, 3, 4, 5, or 6 hepatitis C
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Patient must not be on a concurrent direct acting hepatitis C agent or ribavirin
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request
- Dose must not exceed 3 tablets per day
- Patient must have one of the following:
  - Advanced fibrosis (Metavir F3 or greater)
  - Compensated cirrhosis
  - Organ transplant
  - Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis)
  - Proteinuria
  - Nephrotic syndrome
  - Membranoproliferative glomerulonephritis
- Patient must not have moderate or severe hepatic impairment (Child-Pugh class B or C)
- Patient must not be concurrently prescribed atazanavir or rifampin
- For all genotypes: the PDL preferred drug, which covers that specific genotype, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines
- Patient must be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment

CRITERIA FOR RENEWAL (must meet all of the following):
- Prescriber must document adherence by patient of greater than or equal to 90%
- Must meet one of the following:
  - <u>Genotype 1 (one of the following):</u>
    - Treatment naïve AND without cirrhosis – **8 weeks total duration**
    - Treatment naïve AND with compensated cirrhosis (Child-Pugh A) – **12 weeks total duration**
    - Without cirrhosis AND prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor – **8 weeks total duration**
    - With compensated cirrhosis (Child-Pugh A) AND prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor – **12 weeks total duration**

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	▪ Without cirrhosis or with compensated cirrhosis (Child-Pugh A) AND prior treatment experience with a regimen containing an NS3/4A PI* without prior treatment with an NS5A inhibitor – **12 weeks total duration** ▪ Without cirrhosis or with compensated cirrhosis (Child-Pugh A) AND prior treatment experience with a regimen containing an NS5A inhibitor** without prior treatment with an NS3/4A PI – **16 weeks total duration** * simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and ribavirin **ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin o Genotype 2, 4, 5, or 6 (one of the following): ▪ Treatment naïve AND without cirrhosis – **8 weeks total duration** ▪ Treatment naïve AND with compensated cirrhosis (Child-Pugh A) – **12 weeks total duration** ▪ Without cirrhosis AND prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor – **8 weeks total duration** ▪ With compensated cirrhosis (Child-Pugh A) AND prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor – **12 weeks total duration** o Genotype 3 (one of the following): ▪ Treatment naïve AND without cirrhosis – **8 weeks total duration** ▪ Treatment naïve AND with compensated cirrhosis (Child-Pugh A) – **12 weeks total duration** ▪ Without cirrhosis or with compensated cirrhosis (Child-Pugh A) AND prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor – **16 weeks total duration** LENGTH OF APPROVAL FOR GLECAPREVIR/PIBRENTASVIR: 4 weeks **Public Comment:** Laura Hill with Abbvie suggested removal of 'for both agents' at the end of the first bullet point under 'Criteria for Renewal'. As Mavyret is a fixed dose combination, adherence would be the same for both agents. **Board Discussion:** The Board agreed to the change.	
D. New Prior Authorization (PA) Criteria 2. Haegarda® (C1 esterase inhibitor [human]) i. Prior Authorization Criteria	**Background:** Haegarda is a plasma-derived concentrate of C1 Esterase Inhibitor (Human) (C1-INH) indicated for routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Ms. Dowd moved to approve as amended. Dr. Heston seconded the motion. The criteria were approved as amended unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Initial Approval: October 11, 2017 CRITERIA FOR PRIOR AUTHORIZATION Haegarda® (C1 esterase inhibitor, human) PROVIDER GROUP: Pharmacy Professional MANUAL GUIDELINES: The following drug requires prior authorization: C1 esterase inhibitor, human (Haegarda®) CRITERIA FOR PRIOR AUTHORIZATION FOR C1 ESTERASE INHIBITOR: (must meet all of the following) • Patient must have a diagnosis of Hereditary Angioedema (HAE), with provider submitting documentation that diagnostic testing was completed • Must be used for routine prophylaxis against angioedema attacks in patients with HAE • Patient must be 12 years of age or older LENGTH OF APPROVAL: 12 months **Public Comment:** None. **Board Discussion:** Discussion concerning the last bullet: 'Must be initially administered by a health care professional in an outpatient or home health setting with subsequent administration by only specific persons trained who have demonstrated competence'. Phil King with Pfizer asked if there is a reason for these instructions as it is not on any of their similar agents. The Board noted they want to achieve the patient to be properly trained in administering their mediations. The package insert does have the specific instructions for training. With that in place, the Board decided to remove the last bullet line. Ms. Grant will bring back the other C1 Esterase Inhibitor agents to have the Board approve removal of that instruction on those critera.	
D. New Prior Authorization (PA) Criteria 3. Idhifa® (enasidenib) i. Prior Authorization Criteria	**Background:** Idhifa is an isocitrate dehydrogenase-2 inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Ms. Dowd moved to approve as written. Dr. Heston seconded the motion. The criteria were approved as written unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Initial Approval: October 11, 2017 CRITERIA FOR PRIOR AUTHORIZATION Idhifa® (enasidenib) PROVIDER GROUP: Professional MANUAL GUIDELINES: The following drug requires prior authorization: Enasidenib (Idhifa®) CRITERIA FOR APPROVAL: (must meet all of the following) • Patient must have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation, as detected by an FDA-approved test • Patient must be 18 years of age or older • Prescribed by, or in consultation with, an oncologist or hematologist • Patient must (one of the following): o Females: not be pregnant or breastfeeding and be advised to not become pregnant for at least 1 month after the final dose o Males: advised to use effective contraception (e.g. condoms) during treatment and for at least 1 month after the final dose LENGTH OF APPROVAL: 12 months Notes: • Information on FDA-approved tests for the detection of IDH2 mutations in AML is available at http://www.fda.gov/CompanionDiagnostics. **Public Comment:** Amanda Weber with Celgene offered to be available for any questions. **Board Discussion:** Dr. Zhou asked if the males/females statements followed guidelines set at the previous DUR meeting. Dr. DeRuiter confirmed the wording.	
D. New Prior Authorization (PA) Criteria 4. Motofen® (difenoxin/atropine) i. Prior Authorization Criteria	**Background:** Motofen is indicated as adjunctive therapy in the management of acute nonspecific diarrhea and acute exacerbations of chronic functional diarrhea. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Ms. Dowd moved to approve as written. Dr. Heston seconded the motion. The criteria were approved as written unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Initial Approval: October 11, 2017 CRITERIA FOR PRIOR AUTHORIZATION Motofen® (difenoxin/atropine) PROVIDER GROUP: Pharmacy MANUAL GUIDELINES: The following drug requires prior authorization: Difenoxin/Atropine (Motofen®) CRITERIA FOR APPROVAL (must meet all of the following): • Patient must have tried and failed diphenoxylate/atropine (Lomotil) • Patient must be 12 years of age or older • Dose must not exceed 8 tablets per day • Treatment duration does not exceed 48 hours • Diagnosis is not attributable to diarrhea associated with organisms that penetrate the intestinal mucosa (e.g. toxigenic E. Coli, Salmonella spp, Shigella) and pseudomembranous colitis associated with broad-spectrum antibiotics LENGTH OF APPROVAL: 1 fill **Public Comment:** None. **Board Discussion:** None.	
D. New Prior Authorization (PA) Criteria 5. Ocrevus® (ocrelizumab) i. Prior Authorization Criteria	**Background:** Ocrevus is CD20-directed cytolytic antibody indicated for the treatment of patients with relapsing or primary progressive forms of multiple sclerosis. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Ms. Dowd moved to approve as written. Dr. Unruh seconded the motion. The criteria were approved as written unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Initial Approval: October 11, 2017 CRITERIA FOR PRIOR AUTHORIZATION Ocrevus™ (ocrelizumab) PROVIDER GROUP Professional MANUAL GUIDELINES The following drug requires prior authorization: Ocrelizumab (Ocrevus®) CRITERIA FOR APPROVAL (must meet all of the following): • Patient must have a diagnosis of relapsing or primary progressive forms of multiple sclerosis (MS) (i.e., RRMS or PPMS) • Patient must be 18 years of age or older • Must be prescribed by or in consultation with a neurologist • Patient must not have active hepatitis B virus (HBV), confirmed by positive results for HBsAg and anti-HBV tests • Must not be using with other disease modifying agents (DMA) for MS LENGTH OF APPROVAL: 12 months Notes: • Recommended dosing: Initial dose: 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion. Subsequent doses: single 600 mg intravenous infusion every 6 months. • Prior to initiating OCREVUS, perform Hepatitis B virus (HBV) screening. OCREVUS is contraindicated in patients with active HBV confirmed by positive results for HBsAg and anti-HBV tests. For patients who are negative for surface antigen [HBsAg] and positive for HB core antibody [HBcAb+] or are carriers of HBV [HBsAg+], consult liver disease experts before starting and during treatment. • Administer pre-medication (e.g., methylprednisolone or an equivalent corticosteroid, and an antihistamine) to reduce the frequency and severity of infusion reactions. The addition of an antipyretic (e.g., acetaminophen) may also be considered. • Administer all necessary immunizations at least 6 weeks prior to treatment initiation. **Public Comment:** Blake Baretsky with Genentech offered to be available to answer any questions. **Board Discussion:** None.	
D. New Prior Authorization (PA) Criteria 6. Tremfya® (guselkumab) i. Prior Authorization Criteria	**Background:** Tremfya is an interleukin-23 blocker indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Ms. Dowd moved to approve as written. Dr. Heston seconded the motion. The criteria were approved as written unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Initial Approval: October 11, 2017 CRITERIA FOR PRIOR AUTHORIZATION Tremfya™ (guselkumab) PROVIDER GROUP: Pharmacy Professional MANUAL GUIDELINES: The following drug requires prior authorization: Guselkumab (Tremfya™) CRITERIA FOR MODERATE TO SEVERE PLAQUE PSORIASIS: (must meet all of the following) • Patient must have a diagnosis of moderate to severe plaque psoriasis • Patient must be 18 years or older • Patient must have failed to respond or have lost response to other systemic therapies • Must be prescribed by or in consultation with a Dermatologist or Rheumatologist • Evaluation for latent tuberculosis infection with TB skin test prior to initial PA • Patient has not taken another biologic agent (see attached table) in the past 30 days • The patient has taken an oral DMARD agent for the treatment of plaque psoriasis (see attached table) • Patient is a candidate for systemic therapy or phototherapy LENGTH OF APPROVAL: 12 MONTHS Notes: • Recommended dose is 100 mg at Week 0, Week 4, and every 8 weeks thereafter **Public Comment:** None. **Board Discussion:** None.	
D. New Prior Authorization (PA) Criteria 7. Triptodur® (triptorelin) i. Prior Authorization Criteria	**Background:** Triptodur is a gonadotropin releasing hormone (GnRH) agonist indicated for the treatment of pediatric patients 2 years and older with central precocious puberty. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Dr. Unruh moved to approve as written. Dr. Heston seconded the motion. The criteria were approved as written unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Initial Approval: October 11, 2017 CRITERIA FOR PRIOR AUTHORIZATION Triptodur® (triptorelin) PROVIDER GROUP: Professional MANUAL GUIDELINES: The following drug requires prior authorization: Triptorelin (Triptodur®) CRITERIA FOR APPROVAL (must meet all of the following): • Patient must have a diagnosis of central precocious puberty must be confirmed with both of the following: o Hormone Evaluation: ▪ After GnRH or leuprolide administration, a LH (luteinizing hormone) level of > 5 U/L, OR ▪ Basal (no stimulation test) serum LH > 5 U/L, OR ▪ Basal (no stimulation test) LH > 0.3 U/L using ultra-sensitive assays (chemiluminescence immunoassay) o Bone age advanced one year beyond the chronological age • Patient must be at least 2 years of age AND below age 11 for females and age 12 for males • Patient must have onset of secondary sexual characteristics before 8 years of age in females and 9 years of age in males • Dose must not exceed a single intramuscular injection of 22.5 mg once every 24 weeks LENGTH OF APPROVAL: 12 months **Public Comment:** None. **Board Discussion:** None.	
D. New Prior Authorization (PA) Criteria 8. Bineura® (cerliponase alfa) i. Prior Authorization Criteria	**Background:** Brineura is a hydrolytic lysosomal N-terminal tripeptidyl peptidase indicated to slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency. The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Dr. Unruh moved to approve as written. Ms. Dowd seconded the motion. The criteria were approved as written unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Initial Approval: October 11, 2017 CRITERIA FOR PRIOR AUTHORIZATION Brineura™ (cerliponase alfa) PROVIDER GROUP Professional MANUAL GUIDELINES The following drug requires prior authorization: Cerliponase alfa (Brineura™) CRITERIA FOR APPROVAL (must meet all of the following): • Patient must have a diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), a form of Batten Disease, also known as tripeptidyl peptidase 1 (TPP1) deficiency • Patient must be between the ages of 3 and 8 years of age • Patient must not have any of the following: o Acute intraventricular access device-related complications (e.g., leakage, device failure, or device-related infection) o Ventriculoperitoneal shunt • Must be prescribed by a neurologist • Must be administered in a facility that has been properly trained on how to administer the medication LENGTH OF APPROVAL: 12 months Notes: • Recommended dose: 300 mg administered once every other week by intraventricular infusion. Brineura is administered into the cerebrospinal fluid (CSF) by infusion via a surgically implanted reservoir and catheter (intraventricular access device). • Brineura is not indicated for use in adults **Public Comment:** None. **Board Discussion:** None.	
D. New Prior Authorization (PA) Criteria 9. Rydapt® (midostaurin) i. Prior Authorization Criteria	**Background:** Rydapt is kinase inhibitor indicated for the treatment of adult patients with acute myeloid leukemia (AML) with a positive FLT3 mutation, aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL). The prior authorization criteria are being proposed to ensure appropriate use based upon the FDA-approved labeling information and be consistent with similar agents.	Ms. Dowd moved to approve as written. Dr. Heston seconded the motion. The criteria were approved as written unanimously.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
	Initial Approval: October 11, 2017 CRITERIA FOR PRIOR AUTHORIZATION Rydapt® (midostaurin) PROVIDER GROUP: Pharmacy MANUAL GUIDELINES: The following drug requires prior authorization: Midostaurin (Rydapt®) CRITERIA FOR INITIAL APPROVAL (must meet all of the following): • Patient must have one of the following: o Newly diagnosed with acute myeloid leukemia (AML) that is FLT3 mutation-positive, as detected by an FDA-approved test, and in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation o Aggressive systemic mastocytosis (ASM) o Systemic mastocytosis with associated hematological neoplasm (SM-AHN) o Mast cell leukemia (MCL) • Patient must be 18 years of age or older • Must be prescribed by or in consultation with an oncologist • Patient must (one of the following): o Females: not be pregnant (verified negative pregnancy test within 7 days prior to initiating treatment for those of reproductive potential) or breastfeeding and be advised to not become pregnant or breastfeed for at least 4 months after the final dose o Males: advised to use effective contraception (e.g. condoms) during treatment and for at least 4 months after the final dose LENGTH OF APPROVAL: 12 months Notes: • AML: o Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML. o Newly diagnosed AML refers to those who are treatment naïve. o FLT3 has 2 subtypes of mutations: ITD, TKD. Information on FDA-approved tests for the detection of FLT3 mutation in AML is available at: http://www.fda.gov/CompanionDiagnostics. o Dosing: Rydapt 50 mg twice daily with food on Days 8-21 in combination with daunorubicin (60 mg/m2 daily on Days 1 to 3) /cytarabine (200 mg/m2 daily on Days 1 to 7) for up to two cycles of induction and high dose cytarabine (3 g/m2 every 12 hours on Days 1, 3 and 5) for up to four cycles of consolidation, followed by continuous Rydapt or placebo treatment according to initial assignment for up to 12 additional 28-day cycles. **Public Comment:** Jeanie Brown with Novartis spoke on behalf of Rydapt. **Board Discussion:** Some discussion on inpatient/hospital criteria with the Board deciding not to include that bullet information.	
E. Mental Health Medication	**Background:**	

<table>
<tr><th>TOPIC</th><th>DISCUSSION</th><th>DECISION AND/OR ACTION</th></tr>
<tr><td>Advisory Committee (MHMAC)
1. Multiple Concurrent Mood Stabilizers)
i. Prior Authorization Criteria</td><td>At the August 2017 MHMAC meeting, the committee approved the criteria for use of multiple concurrent mood stabilizers.
Initial Approval: October 11, 2017
CRITERIA FOR PRIOR AUTHORIZATION
Use of Multiple Concurrent Mood Stabilizers
PROVIDER GROUP Pharmacy
MANUAL GUIDELINES The following drug requires prior authorization:
Carbamazepine (Epitol®, Tegretol®, Tegretol XR®, Carbatrol®, Equetro®)
Lamotrigine (Lamictal-plain, XR, ODT®)
Lithium (Eskalith®, Lithobid®, Lithane®)
Oxcarbazepine (Trileptal®, Oxtellar XR®)
Topiramate (Topamax®, Topamax Sprinkle®, Qudexy XR®, Trokendi XR®, Qsymia®*)
Valproic Acid (Depacon®, Depakene®, Depakote®-plain, ER, sprinkle, Divalproex®)
*Qsymia® is a combination of topiramate and phentermine.
CRITERIA FOR PRIOR AUTHORIZATION FOR PATIENTS RECEIVING MULTIPLE MOOD STABILIZERS CONCURRENTLY:
• Four or more different mood stabilizers used concurrently for greater than 60 days will require a prior authorization:
o At least one medication must be prescribed by or in consultation/collaboration with a neurologist
o Patient must have a documented seizure related diagnosis within the previous 365 days
LENGTH OF APPROVAL: 12 months
<u>Public Comment:</u>
None.
<u>Board Discussion:</u>
The Board discussion was around the few current patients that this would affect however, this offers a safeguard for future patients as well.</td><td>Ms. Dowd moved to approve as written.

Dr. Heston seconded the motion.

The criteria were approved as written unanimously.</td></tr>
<tr><td>F. Miscellaneous Items
1. Fee-for-Service Annual Program Assessment
i. Presentation</td><td><u>Background:</u>
The annual program assessment for the Medicaid fee-for-service population will be presented to show drug trends over the past state fiscal year.
Dr. DeRuiter presented the annual report.
<u>Board Discussion:</u>
None.</td><td></td></tr>
<tr><td>IV. Open Public Comment:</td><td>None.</td><td></td></tr>
<tr><td>V. Adjourn:</td><td>Ms. Dowd moved to adjourn.
Dr. Rice seconded the motion.
The motion to adjourn was approved unanimously by voice count ‘Ayes’.</td><td>Dr. Mittal adjourned the October 11, 2017 DUR Meeting at 12:09 pm.</td></tr>
<tr><td colspan="3">The next DUR Board meeting is scheduled for January 10, 2018.
Public Comment: is limited to five minutes per product; additional time will be allowed at the DUR Board’s discretion. Informal comments will be accepted from members of the audience at various points in the agenda.</td></tr>
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